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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,936	01/03/2000	THOMAS G. WILSON	082584/0107	6645

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EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/20/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/402,936		WILSON ET AL.	
	Examiner		Art Unit	
	David Guzo		1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 and 30-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 18-29 and 42-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,7</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Applicant's election with traverse of Group I, claims 1-14, 18-29 and 42-51 in Paper No. 15 is acknowledged. The traversal is on the ground(s) that the special technical feature linking the different groups is the polynucleotide(s) encoding a bHLH-PAS polypeptide. Applicants assert that since said polynucleotide(s) encodes the polypeptide(s) of group II, there is no lack of unity between groups I and II. Applicants assert that since the methods of Groups III-IV use the polynucleotides or polypeptides representing the special technical feature linking the inventions, restriction between these groups is improper. This is not found persuasive because the polypeptides of Group II do not share the special technical feature of the polynucleotides of Group I. Each is a structurally, biochemically and functionally distinct molecule with each capable of supporting separate patents. Since the polypeptides of Group II do not share any biochemical or structural relationship with the polypeptides of Group II, they do not share a common special technical feature. With regard to Group III, this method involves detection of altered bHLH-PAS sequences in JH-resistant individuals and hence defines an advance over that of Group I. With regard to Group IV, said method involves the screening of compounds that bind bHLH-PAS polypeptides and since the polypeptides do not share a common special technical feature with the polynucleotides of Group I, restriction here is required.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-17 and 30-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable

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generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. 08/971,188 and 08/843,205, filed 11/17/97 and 4/14/97, respectively. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months

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from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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Claims 42, 48 and 49 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3 of prior U.S. Patent No. 6,326,165. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14, 43, 50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-24 of U.S. Patent No. 6,326,165 (hereafter the '165 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite the same polynucleotides, expression vectors and host cells containing said expression vectors. Claims 1, 6-14, 43 and 50 are generic to all that is recited in claims 1, 4-24 of the '165 patent. That is claims 1, 4-24 fall entirely within the scope of claims 1, 6-14, 43 and 50, in other words, claims 1, 6-14, 43 and 50 are anticipated by claims 1, 4-24 of the '165 patent. Specifically, the patented polynucleotides encoding specific bHLH-PAS proteins involved in binding JH III are isolated from *Drosophila* (fruit flies),

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encode the same proteins (SEQ ID NO:s 4 and 5) as instantly claimed, the polynucleotides are contained in expression vectors which are in the same host cells and said host cells are cultured so as to produce the same bHLH-PAS proteins. The instant claims, which are drawn to any polynucleotides encoding bHLH-PAS proteins involved in JH III binding are anticipated by the specific polynucleotides recited in the '165 patent. With regard to SEQ ID NO:7, the instant claims differ from the patented claims (See claim 7 in the '165 patent) only in the recitation of SEQ ID NO:7 in the context of open language rather than closed language; however, the patented claim can anticipate the instant claims because the instant claims also read on a nucleic acid which can contain only the recited sequence of SEQ ID NO:7.

With regard to instant claims 2-5, the claims read on polynucleotides which are capable of hybridizing to SEQ ID NO:s 1-3, 6 or capable of hybridizing to polynucleotides encoding SEQ ID NO:4-5 or capable of hybridizing to a riboprobe which is the reverse transcript of a portion of SEQ ID NO:1 under stringent conditions. However, these claims read on polynucleotides which are identical to SEQ ID NO:s 1-3, 6 or sequences which encode SEQ ID NO:s 4-5 and hence are anticipated by the claims in the '165 patent.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Turner et al.

Applicants claim an isolated polynucleotide (*Met-JHR* gene) that encodes a bHLH-PAS polypeptide that is involved in binding JH III, wherein the polynucleotide can be from a dipteran species such as a fruit fly.

Turner et al. (Cited by applicants, Archives of Insect Biochemistry and Physiology, Vol. 30, 1995, pp. 133-147, see whole article, particularly p. 136) discloses isolated cosmid clones that contain the *Met-JHR* gene from the fruit fly *Drosophila melanogaster*. It is noted that applicants also indicate that Turner et al. prepared cosmid clones which contained the *Met-JHR* gene from *Drosophila* on p. 61 of the instant specification. Turner et al. therefore teaches the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-14, 18-29 and 42-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et al.

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Wilson et al. (U.S. Patent 6,326,165, see whole document, particularly Claims 1-24 and columns 3-9) is the U.S. parent of the instant application and recites the same invention as instantly claimed. This rejection is being made because applicants have not perfected the priority claim on the first page of the specification. Perfection of the priority claim will obviate this rejection.

35 USC 112,1st Paragraph Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-8, 11-14, 18-29, 43-47, 50-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim any isolated polynucleotide encoding a bHLH-PAS polypeptide that is involved in binding juvenile hormone III (JH III) or said polynucleotide isolated from any of several insect orders, dipterans or any fruit fly. Applicants also claim expression vectors (and cells containing said vectors) containing said polynucleotides and a method of making said polypeptides comprising culturing cells containing vectors encoding the bHLH-PAS polypeptides. Applicants also claim methods of screening compounds that specifically bind any bHLH-PAS polypeptide or a *Met*-JHR alternatively

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spliced isoform and a nucleic acid probe comprising a genetic locus in a bHLH-PAS gene encoding a polypeptide associated with JH analog sensitivity and resistant traits and involved in binding JH III. Applicants also claim a sequence from the *Met* gene from *D. erecta* (SEQ ID NO:7) and sequences capable of hybridizing to SEQ ID NO:7 under stringent conditions. The claims therefore read on a genus of nucleic acid sequences encoding any bHLH-PAS polypeptides involved in binding JH III or bHLH-PAS polypeptides from a dipteran species or any fruit fly or alternatively spliced isoforms of *Met*-JHR and methods of using these sequences to screen for compounds that bind these polypeptides. The claims also read on a genus of probe molecules comprising loci involved with JH analog sensitivity and resistance traits as well as any molecule having SEQ ID NO:7. Applicants provide a written description of the *Met*-JHR gene (cDNA and genomic) from *D. melanogaster* and a partial sequence of the *Met* gene from the species *D. erecta* (SEQ ID NO:7).

The written description requirement for a claimed genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicant was in possession of the claimed genus.

In the instant case, applicants have disclosed sequences encoding a JH receptor (*Met*-JHR) from *D. melanogaster* and a partial sequence of a putative *Met*-JHR from *D.*

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erecta. These proteins belong to a diverse group of "basic helix loop helix" proteins (bHLH-PAS). While applicants disclose several potentially relevant motifs in the Met-JHR molecule, it is unclear if they are relevant to JH binding and methoprene resistance. Applicants provide no description of and the prior art does not disclose the functional motifs of *Met*-JHR proteins. Therefore, applicants claim the nucleic acid sequences encoding JHRs by functional characteristics, without any known or disclosed correlation between that function and the structure of the sequence. Given the broad scope of the claimed subject matter (the narrowest claims read on *Met*-JHR genes from hundreds of different species, e.g. fruit flies, while the broadest claims read on the gene sequences from millions of different insect species), it must be assumed, absent evidence to the contrary, that the members of the claimed genus would vary widely in their identifying characteristics. It is noted that a comparison between the relevant portions of the *Met*-JHR coding sequence from *D. melanogaster* and the partial coding sequence of the putative *Met*-JHR gene from *D. erecta* shows some significant sequence differences in portions of the molecules as well as considerable homology in other portions. Also, it is unclear if the portion of the putative *Met*-JHR gene from *D. erecta* encodes a portion of the polypeptide that is functionally important with regard to the polypeptide acting as JH receptor.

With regard to claims reading on methods of screening for compounds that bind the Met-JHR involving use of a *Met*-JHR alternatively spliced isoform, neither applicants nor the prior art provide a description of said alternatively spliced isoforms and it is unclear if they exist. With regard to probes which are specific for detecting RFLPs that

discriminate between JH-sensitive and JH resistant individual insects, it is noted that the genetic loci in a bHLH-PAS gene involved in JH III binding that are involved in determining JH-resistance vs. JH-sensitivity are unknown and therefore probes for detecting RFLPs are likewise unknown and have not been described. Applicants have presented no examples of *Met*-JHR specific probes able to distinguish between JH-sensitive and JH-resistant insects. With regard to SEQ ID NO:7, said sequence is a fragment of a putative *Met*-JHR gene from *D. erecta*. Since the claims read on a sequence **comprising** SEQ ID NO:7 or sequences encoding a bHLH-PAS polypeptide which is involved in binding JH III (*Met*-JHR) and are capable of hybridizing to SEQ ID NO:7 under stringent conditions, the claim reads on the undescribed complete cDNA or genomic version of the sequence encoding the putative *Met*-JHR protein. The disclosed portion of the *D. erecta Met*-JHR sequence provides no guidance on the remaining coding and regulatory sequences of the gene and indeed, these must be determined empirically. Therefore, applicants have not provided a written description of the genus of sequences encompassed by the claims. It is noted that claims 44-47 recite nucleotide positions in SEQ ID NO:7 which cannot be present in the sequence (i.e. claim 44 recites positions 1 to 1291 of SEQ ID NO:7 but there are only 232 nucleotides in SEQ ID NO: 7). These claims are included in the rejection on the assumption that applicants mean to claim actual portions of SEQ ID NO:7.

35 USC 112, 2nd Paragraph Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4, 6, 9, 44-47, 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-4 and 51 are vague in that applicants recite isolated polynucleotides which hybridize to specific SEQ ID NO:s under "stringent conditions". The term "stringent conditions" is a subjective one and applicants do provide a specific definition for "stringent conditions". While applicants provide "exemplary stringent conditions" on p. 31 of the specification, the instant claims are not limited to these conditions and The use of the term "exemplary" only means that these are one example of the conditions which can fall under "stringent conditions". Without a definition of the term, it is unclear what nucleic acids would be encompassed by the claimed language and hence the metes and bounds of the claims are unclear.

Claim 6 is vague in that there is no antecedent basis for the term "said insect" in claim 1.

Claim 9 is vague in that applicants recite a polypeptide which can be SEQ ID NO:3. SEQ ID NO:3 is a **polynucleotide** sequence. Possibly applicants mean to claim SEQ ID NO:s 4 and 5 rather than SEQ ID NO:s 3 and 4.

Claims 44-47 are vague in that they recite nucleotide numbers of 1 to 1291, 1 through 1513, 3733 to 6235 and 4302 to 6235; however, **SEQ ID NO:7 only contains 232 nucleotides.**

Duplicate Claims

Claim 43 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 50. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The Declaration claims benefit for U.S. application 08/843,205 under 35 USC 119(a)-(d) or 365(b) rather than 35 USC 120.

Sequence Rules

An amino acid sequence that appears on p. 68, line 13, of the specification is not identified by SEQ ID NO.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-

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1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be sent directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
May 17, 2003

DAVID GUZO
PRIMARY EXAMINER
